REMARKS

The claims have been amended to limit the nucleic acid encoding the amino acid sequence of SEQ ID NO: 24 to that sequence *per se*. This amendment should dispose of all the outstanding art rejections as presently pending claims that are limited to recombinant materials limited to this sequence (claims 19, 22-23 and 25-26) are not subject to an art rejection. Clearly the amendment to claims 1 and 14 is supported by these previously pending dependent claims. The wording of claims 18 and 19 has been changed simply to conform to the wording of the previous claim, and claim 14 has been further amended as suggested by the Office.

No new matter has been added and entry of the amendment is respectfully requested.

Applicants appreciate the acknowledgement of their Information Disclosure Statement. Applicants also appreciate the withdrawal of certain rejections previously made.

The Rejection Under 35 U.S.C. §§ 101/112, First Paragraph

Both the rejection under 35 U.S.C. § 101 and under § 112, first paragraph, are based on the same rationale – a putative lack of utility with regard to the claimed recombinant materials. As best applicants can understand, the Office does not consider it useful to provide materials for a screening assay for modulators of T-type channels characterized by α_{1G} because there is no guarantee that the modulators thus identified will be useful in treating any disease or condition. Of course, there is no guarantee. It is in the very nature of screening methods that a large number of candidate compounds will be identified, only a small fraction of which will actually wind up being approved for use, or even tested in the clinic. That hardly means that screening assays are not useful. If they

were not useful, then why is every pharmaceutical company and every biotechnology company expending their resources by conducting such assays?

Applicants are aware, of course, that every case stands on its own merits, but surely it is unfair and illogical to apply different standards to comparable cases. Applicants believe they have a right to expect some uniformity and fairness in the disposition of their applications by the Office. Thus, applicants believe that if the Office issued U.S. 5,401,629 and U.S. 5,837,479 which also provide screens for identifying compounds, most of which will turn out not to be successful, it is inconsistent to reject the present claims based on lack of utility. As to the distinction drawn between the present case and U.S. 5,837,479, it is not the case that there is no nexus between the claimed methods and a specific condition. Applicants have already pointed out that their specification on page 9, lines 19-20, points out specific conditions for which the identified compounds are candidate therapeutics. Of course, the compounds identified are only candidates for such therapies, as was the case in U.S. patent 6,358,706.

Again, applicants emphasize that they are aware that the Office takes the position that each case must stand on its merits. Applicants agree with that position. However, applicants also believe that the same criteria should be applied uniformly by the Office so that applicants have an expectation of what is and what is not acceptable as a showing for utility.

In the end, applicants are puzzled why a screening method which is designed to identify candidate therapeutics for specifically identified conditions (as set forth in the specification) would not be the standard for utility. The utility is specific – it is designed to result in a group of candidates for treatment of specific diseases. By definition, this is substantive, and it is certainly credible.

The claims, of course, are not drawn to these methods *per se*, but rather to materials that are useful, indeed indispensable, in conducting such methods. Therefore, these materials have utility as described herein.

Applicants wish to address several specific points made by the Office in the context of the rejection. First, the Office asserts that applicants have not presented statistically relevant data documenting the activity of a compound or documentary evidence establishing a nexus between the claimed nucleic acids and a specific disease or convincing arguments or reasoning. Applicants disagree. In the first place, no compounds are being claimed. Secondly, the specification does state that there is a nexus between the malfunction of calcium ion channels for which the recombinant materials are claimed and specific diseases on page 9, lines 19-20. Documentary evidence of this linkage can be found, for example, in U.S. patent 6,358,706 which has a § 102(e) date prior to the date to which the Office assigns applicants priority.

The Office indicates that "applicant has also failed to disclose a nexus between any of the diseases and conditions listed on page 5 of the specification and the instantly claimed nucleic acids." This is simply not true. The nexus is explicitly stated on page 5, lines 15-17, and on page 9, lines 19-20. The nucleic acids encode ion channels useful in screening assays for candidate therapeutics for these conditions.

Further, the Office states "there is no indication that expression of the nucleic acids or their encoded proteins or the activity of these proteins are different in any of those conditions." Again, the Office has simply refused to believe the straightforward statements in the specification.

As to the assertion that applicants have admitted that no compounds useful in treating these conditions have yet been identified is not seen as either an admission that no such compounds exist,

or that this implies that the screening tool is not useful. As the Office is certainly aware, it takes years to develop a pharmaceutical that is useful in treating any condition. Development of a screening tool is a first step in this process, and a very useful first step commonly employed, at considerable expense, by the industry as a whole.

For these reasons, applicants believe the rejection for lack of utility, whether made under 35 U.S.C. § 101 or § 112, is in error and should be withdrawn.

Priority

The issue of priority to earlier applications is not germane to the present rejection.

The Rejection Under 35 U.S.C. §§ 102/103

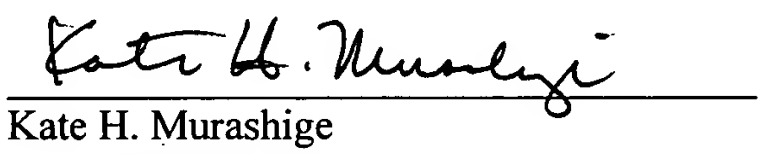
The rejection of claims 1, 4-6 and 14 over the art is overcome by amendment. The limitations of claims 19 and 26, not rejected over the art, have been added to these claims, which are therefore rendered free of the art as well.

Conclusion

Applicants respectfully request reconsideration of the proposition that screening tests designed to identify candidates for treating diseases that are mediated by specific T-type calcium ion channels are not useful. In order to develop drugs to treat these conditions, which conditions are specifically set forth in the specification, the screening methods enabled by the claimed compositions are a necessary and useful first step. The rejection of the claims over the art has been obviated by amendment. Therefore, it is believed that claims 1-2, 4-6, 14 and 18-26, all pending claims herein, are in a position for allowance and passage of these claims to issue is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 381092000721.

Respectfully submitted,

Dated: August 11, 2005 By: 

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